

IN THE CLAIMS

The status of each claim is listed below:

Claims 1-23: (Canceled).

Claim 24 (New): A process of lyophilization for the preparation of a piroxicam: β -cyclodextrin inclusion compound in a 1:2.5 molar ratio, comprising:

- a) dissolving piroxicam and β -cyclodextrin in the molar ratio of 1 to 2.5 and ammonium hydroxide in water brought to a temperature of at least 60 °C;
- b) bringing the resulting solution to the temperature of -10 °C of complete freezing;
- c) further lowering the temperature of the frozen solution to at least -20 °C; and
- c) drying the frozen solution under vacuum.

wherein the temperature of -10 °C of complete freezing of the hot solution of step a) is achieved at a cooling rate equal to or higher than 1 °C/min.

Claim 25 (New): The process as claimed in claim 24, wherein the cooling rate is 1.5 °C/min.

Claim 26 (New): The process as claimed in claim 24, wherein the hot solution of step a) is poured on the temperature-controlled shelves of a freeze-dryer, and said shelves of said freeze-dryer are pre-cooled to a temperature of at least -30 °C in order to achieve a cooling rate equal to or higher than 1 °C/min.

Claim 27 (New): The process as claimed in claim 26, wherein the shelves of the freeze-dryer are pre-cooled to a temperature of at least -40 °C.

Claim 28 (New): The process as claimed in claim 24, wherein the temperature is lowered to between -30 and -40 °C.

Claim 29 (New): The process as claimed in claim 24, wherein the hot solution of a) is poured in a dewar filled with liquid nitrogen.

Claim 30 (New): The process as claimed in claim 29, wherein the product obtained is in the form of solid granules.

Claim 31 (New): The process as claimed in claim 24, wherein the step c) of drying is carried out at a temperature of 50-60 °C.

Claim 32 (New): The process as claimed in claim 24, wherein the water in a) is brought to a temperature of at least 70 °C.

Claim 33 (New): The process as claimed in claim 32, wherein the water is brought to a temperature between 70 and 75 °C.

Claim 34 (New): The process as claimed in claim 24, wherein the ammonium hydroxide is used in a concentration of 28-30 % and in a 1:1 ratio (w/w) with respect to piroxicam.

Claim 35 (New): The process as claimed in claim 24, wherein the temperature of complete freezing of the hot solution is achieved in not more than 90 minutes.

Claim 36 (New): The process as claimed in claim 24, which is conducted on an industrial scale.